IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:	**MDL No. 1871**
	:	**Case No. 07-md-01871**
This Document Relates To:	:	
All Third Party Payor Actions	:	

MEMORANDUM OPINION

Rufe, J. **September 3, 2020**

Plaintiffs, United Food and Commercial Workers Local 1776 and Participating Employers Health and Welfare Fund and J.B. Hunt Transport Services, Inc. (collectively, "the Plans"), filed suits against GlaxoSmithKline LLC ("GSK") alleging violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO") and various state consumer protection laws in connection with the marketing of Avandia.[1] These actions were incorporated into the In re Avandia Marketing, Sales Practices and Products Liability Multi-District Litigation ("MDL"). In connection with a motion for summary judgment that has since been resolved, certain documents were filed under seal pursuant to a pretrial protective order. The issue before the Court is whether those documents should remain sealed. The Court previously declined to unseal most of the documents; the Plans appealed those rulings; and the Third Circuit vacated and remanded for

[1] There were originally four third party payor actions to be considered here. These cases were brought by: (1) Allied Services Division Welfare Fund ("Allied") (Civil Action No. 09-730); (2) United Benefit Fund ("UBF") (Civil Action No. 10-5419); (3) UFCW Local 1776 and Participating Employers Health and Welfare Fund ("UFCW") (Civil Action No. 10-2475); and (4) J.B. Hunt Transport Services, Inc. ("J.B. Hunt") (Civil Action No. 11-4013). However, the claims asserted by Allied and UBF have been voluntarily dismissed with prejudice. *See* Doc. Nos. 5033 & 5041. Therefore, the Court will consider GSK's motion with respect to the actions brought by UCFW and J.B. Hunt.

further consideration.[2] GSK now moves to maintain the confidentiality of specific documents pursuant to the Third Circuit's instructions. For the following reasons, GSK's motions will be granted in part and denied in part.

I. BACKGROUND

The MDL was created based on "allegations that certain diabetes drugs manufactured by GSK – Avandia and/or two sister drugs containing Avandia (Avandamet and Avandaryl) – cause an increased risk of heart attack and other physical injury, and that GSK failed to provide adequate warnings concerning that risk."[3] The Plans filed suit on behalf of a proposed nationwide class of health benefit providers that had paid for Avandia. In 2008, the Court entered Pretrial Order No. 10 ("PTO 10"), which governed discovery of confidential materials in the MDL.[4] In 2016, GSK moved for summary judgment as to the Plans' consumer protection claims based on federal preemption, and on the RICO claims based on the failure to identify a distinct RICO enterprise. As part of the summary judgment briefing, the parties filed documents under seal pursuant to PTO 10, and neither party objected at the time. In late 2017, the Court granted GSK's motion for summary judgment.[5]

The Plans appealed and stated that they would seek to unseal certain documents to include them in the Joint Appendix for appeal. GSK then filed two motions before this Court to maintain the seal as to certain documents.[6] The Court granted in part and denied in part both

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[2] *See In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 924 F.3d 662 (3d Cir. 2019).

[3] Doc. No. 1 at 2. All of the cases in the MDL asserting claims of personal injury have been resolved.

[4] Doc. No. 138.

[5] *See* Doc. No. 5152, *vacated and remanded, In re Avandia Mktg., Sales & Prod. Liab. Litig*., 945 F.3d 749 (3d Cir. 2019).

[6] Doc. Nos. 5192 & 5207. The Expert Report, Supplemental Expert Report, and Declaration, of John D. Abramson, as well as the Third Party Payor Plaintiffs' Response to Defendant's Proposed Statement of Undisputed Fact, were all included in the first motion. *See* Ex. A, GSK's Motion to Preserve Confidentiality of Designation of Certain Documents [Doc. No. 5192-1].

motions.[7] The Plans appealed and the Court of Appeals vacated and remanded "this matter to permit the District Court to conduct a detailed review of the challenged documents by applying the proper standard for accessibility under the common law."[8]

On August 5, 2019, GSK filed a Motion for the Continued Sealing of Certain Documents.[9] In this motion, GSK moved to maintain three documents under seal:

1) Expert Report of John David Abramson, M.D.;[10]
2) Supplemental Expert Report of John Abramson;[11] and
3) Declaration of John D. Abramson MD, MSC, Regarding GSK's Motion for Partial Summary Judgment on Preemption.[12]

GSK also moved the Court for the disclosure of redacted versions of a host of documents identified in an attached exhibit in order to protect the privacy interests "of study subjects, GSK employees, and other individuals as required by the European Union's General Data Protection Regulation, and European Medicines Agency Policy 0070."[13]

On November 4, 2019, GSK filed a Motion for the Continued Sealing of the Expert Reports of Donald Austin, Eliot Brinton, and Brian Swirsky.[14] In this motion, GSK moved to maintain five documents under seal:

1) Plaintiff Steering Committee's Generic Expert Report of Donald Austin;[15]

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[7] Doc. Nos. 5201 & 5220.

[8] *In re Avandia*, 924 F.3d at 679 (citing *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 167 (3d Cir. 1993)).

[9] Doc. No. 5259. In a Joint Status Report filed pursuant to a Court Order, the parties identified 24 documents that GSK no longer sought to keep under seal. *See* Doc. No. 5262-1. Therefore, on August 27, 2019, the Court ordered the Clerk of Court to unseal those documents. *See* Doc. No. 5267.

[10] Ex. 146 to the Decl. of Thomas Sobol filed July 1, 2016 [Doc. No. 4907].

[11] Ex. 147 to the Decl. of Thomas Sobol filed July 1, 2016 [Doc. No. 4907].

[12] Ex. 148 to the Decl. of Thomas Sobol filed July 1, 2016 [Doc. No. 4907].

[13] Doc. No. 5259.

[14] Doc. No. 5285.

[15] Ex. 149 to the Decl. of Thomas Sobol filed July 1, 2016 [Doc. No. 4907].

2) Plaintiff Steering Committee's Generic Expert Report of Eliot A. Brinton;[16]
3) Supplemental Expert Statement of Eliot A. Brinton;[17]
4) Plaintiff Steering Committee's Generic Expert Report of Brian Swirsky;[18] and
5) Plaintiff Steering Committee's Generic Supplemental Expert Report of Brian Swirsky.[19]

The Plans oppose both motions, except as to specific redactions of personal information of study subjects and employee telephone numbers, addresses, and ending of email addresses. Pursuant to the mandate of the Court of Appeals, the Court has considered GSK's arguments as to each of the contested documents.[20]

II. LEGAL STANDARD

There are "three distinct standards when considering various challenges to the confidentiality of documents."[21] First, the factors articulated in *Pansy v. Borough of Stroudsburg*[22] apply to the confidentiality of discovery materials pursuant to Federal Rule of Civil Procedure 26.[23] Second, "the more rigorous common law right of access [applies] when discovery materials are filed as court documents. In addition to recognizing fewer reasons to justify the sealing of court records, the public right of access—unlike a Rule 26 inquiry—begins

[16] Ex. 150 to the Decl. of Thomas Sobol filed July 1, 2016 [Doc. No. 4907].

[17] Ex. 151 to the Decl. of Thomas Sobol filed July 1, 2016 [Doc. No. 4907].

[18] Ex. 152 to the Decl. of Thomas Sobol filed July 1, 2016 [Doc. No. 4907].

[19] Ex. 153 to the Decl. of Thomas Sobol filed July 1, 2016 [Doc. No. 4907].

[20] As will be discussed below, to overcome the presumption of access, GSK has made the same argument for all of the expert reports: that the unsealing of the expert reports will lead to harmful results for current Avandia patients. Similarly, GSK's argument for its requested redactions is that the harm it will face in the form of penalties under EU law outweighs the common law presumption of access. Therefore, the Court will balance each claimed harm against the presumption of access and the public's interest in openness. *See In re Avandia*, 924 F.3d at 677 (quoting *Leucadia,* 998 F.2d at 167) (explaining "that careful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants").

[21] *In re Avandia,* 924 F.3d at 670; *see also Purcell v. Gilead Scis., Inc.*, 415 F. Supp. 3d 569, 573 (E.D. Pa. 2019).

[22] 23 F.3d 772, 783–92 (3d Cir. 1994).

[23] *See In re Avandia*, 924 F.3d at 670.

with a presumption in favor of public access."[24] Third, "the First Amendment right of public access attaches to, *inter alia*, civil trials."[25]

Rule 26(c) permits the Court to enter a protective order to shield a party "from annoyance, embarrassment, oppression, or undue burden or expense."[26] "A protective order may apply to all litigation materials—not just those filed in court—because '[c]ourts have inherent power to grant orders of confidentiality over materials not in the court file.'"[27] "The District Court 'must balance the requesting party's need for information against the injury that might result if uncontrolled disclosure is compelled.'"[28] "The proponent of the protective order shoulders '[t]he burden of justifying the confidentiality of each and every document sought to be' sealed" and "must demonstrate that 'good cause' exists for the order."[29] "Good cause means 'that disclosure will work a clearly defined and serious injury to the party seeking closure. The injury must be shown with specificity.'"[30] In deciding whether good cause exists, the Court's

[24] *Id.* (citing *Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 192–93 (3d Cir. 2001)).

[25] *Id.* (citing *Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1061 (3d Cir. 1984)).

[26] Fed. R. Civ. P. 26(c)(1).

[27] *In re Avandia*, 924 F.3d at 671 (quoting *Pansy*, 23 F.3d at 785).

[28] *Id.* (quoting *Pansy*, 23 F.3d at 787).

[29] *Id.* (quoting *Pansy*, 23 F.3d at 786–87).

[30] *Id.* (quoting *Pansy*, 23 F.3d at 786). The Third Circuit has set forth a non-exhaustive list of factors that a court may consider when determining if good cause exists:

1) whether disclosure will violate any privacy interests;
2) whether the information is being sought for a legitimate purpose or for an improper purpose;
3) whether disclosure of the information will cause a party embarrassment;
4) whether confidentiality is being sought over information important to public health and safety;
5) whether the sharing of information among litigants will promote fairness and efficiency;
6) whether a party benefitting from the order of confidentiality is a public entity or official; and
7) whether the case involves issues important to the public.

Glenmede Tr. Co. v. Thompson, 56 F.3d 476, 483 (3d Cir. 1995) (citing *Pansy,* 23 F.3d at 787–91).

analysis "should always reflect a balancing of private versus public interests" and "should articulate on the record findings supporting its decision to grant or deny a protective order."[31]

"Analytically distinct from the District Court's ability to protect discovery materials under Rule 26(c), the common law presumes that the public has a right of access to judicial materials. In both criminal and civil cases, a common law right of access attaches 'to judicial proceedings and records.'"[32] "Whether the common law right of access applies to a particular document or record 'turns on whether that item is considered to be a "judicial record."'"[33] "A 'judicial record' is a document that 'has been filed with the court . . . or otherwise somehow incorporated or integrated into a district court's adjudicatory proceedings.'"[34] Thus, "documents filed in connection with a motion for summary judgment are judicial records" with a "presumptive right of public access."[35]

Because the "strong presumption of openness does not permit the routine closing of judicial records to the public . . . [t]he party seeking to overcome the presumption of access bears the burden of showing 'that the interest in secrecy outweighs the presumption.'"[36] "The movant must show 'that the material is the kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure.'"[37]

"To overcome that strong presumption, the District Court must articulate 'the compelling, countervailing interests to be protected,' make 'specific findings on the record concerning the

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[31] *In re Avandia*, 924 F.3d at 672 (internal quotation and citations omitted).

[32] *Id.* (quoting *In re Cendant Corp.*, 260 F.3d at 192).

[33] *Id.* (quoting *In re Cendant Corp.*, 260 F.3d at 192).

[34] *Id.* (quoting *In re Cendant Corp.*, 260 F.3d at 192).

[35] *Id.* (citations omitted).

[36] *Id.* (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994); *Bank of Am. Nat. Tr. & Sav. Ass'n v. Hotel Rittenhouse Assocs.*, 800 F.2d 339, 344 (3d Cir. 1986)).

[37] *Id.* (quoting *Miller*, 16 F.3d at 551).

effects of disclosure,' and 'provide[] an opportunity for interested third parties to be heard.'"[38] "In delineating the injury to be prevented, specificity is essential."[39] "Broad allegations of harm, bereft of specific examples or articulated reasoning, are insufficient."[40] "[C]areful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants."[41] "To that end, the District Court must 'conduct[] a document-by-document review' of the contents of the challenged documents."[42]

Finally, there is the First Amendment. Although "the public and the press have a First Amendment right of access to civil trials,"[43] it is an "open question in this Circuit whether the First Amendment right of access applies to records of summary judgment proceedings."[44] However, a First Amendment right of access is evaluated under strict scrutiny and "requires a much higher showing than the common law right [of] access before a judicial proceeding can be sealed."[45]

III. DISCUSSION

A. Applicable Standard of Law

Although the Court of Appeals instructed the Court to apply the common law right of access on remand,[46] in both motions, GSK argues that the expert reports are not "judicial records" to which the common law right of access applies because they were not competent to be

[38] *Id.* at 672–73 (quoting *In re Cendant Corp.*, 260 F.3d at 194).

[39] *Id.* at 673 (quoting *In re Cendant Corp.*, 260 F.3d at 194)

[40] *Id.* (quoting *In re Cendant Corp.*, 260 F.3d at 194).

[41] *Id.* at 673 (quoting *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 167 (3d Cir. 1993)).

[42] *Id.* (quoting *Leucadia,* 998 F.2d at 167).

[43] *Id.* (citing *Publicker*, 733 F.2d at 1070).

[44] *Id*.

[45] *Id.* at 673 (quoting *In re Cendant Corp.*, 260 F.3d at 198 n.13).

[46] *See id.* at 669.

considered on summary judgment.[47] Specifically, GSK asserts that the expert reports were not sworn to under penalty of perjury; and that the Austin, Brinton & Swirsky Reports "were written in 2010" and therefore "were irrelevant by the time GSK filed its motion in 2016."[48]

GSK's argument relies on the initial premise that if the documents had an evidentiary defect at the time the summary judgment motion was decided, then they are not "judicial records."[49] Although GSK recognizes that when ruling on its appeal regarding the sealing of almost all of these very expert reports the Third Circuit held that "documents filed in connection with a motion for summary judgment are judicial records,"[50] GSK nonetheless asserts that a different Third Circuit case, *North Jersey Media Group Inc. v. United States*,[51] "explains that the test is more nuanced."[52] GSK relies on language from *North Jersey* suggesting that the relevance

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[47] GSK does not dispute that the requested redactions are subject to the common law right of access. *See* GSK's Mem. Supp. Mot. for Continued Sealing [Doc. No. 5259] at 18 ("The disclosure of personal data, and particularly medical information, is precisely the type of harm that overcomes the public's right to access judicial records.").

[48] GSK's Mem. of Law in Supp. of Mot. for the Continued Sealing of the Expert Reports of Austin, Brinton, and Swirsky [Doc. No. 5285] at 4–7. The Plans explain that at summary judgment they argued that GSK misrepresented Avandia's cardiovascular profile, promoting the drug as cardio-protective when it actually carried significant cardiovascular risk, and that the expert reports were relevant to the question of "[w]ould the plaintiffs have purchased Avandia had GSK been honest about the drug's cardiovascular profile?" Pls.' Mem. in Opp. to GSK's Motion for the Continued Sealing of the Expert Reports of Austin, Brinton, and Swirsky [Doc. No. 5289] at 6. GSK responds that this question was not relevant to the actual issues at summary judgment, including "whether plaintiffs' cardiovascular benefits claims were part of their case from the beginning." GSK's Reply in Supp. of its Mot. for the Continued Sealing of the Expert Reports of Austin, Brinton, and Swirsky [Doc. No. 5293] at 2. However, at summary judgment, the Court explained that "[t]he crux of Plaintiffs' claims is that GSK concealed information about Avandia's cardiovascular risk by stating that the product was safe and effective for patients, and that but for this concealment, Plaintiffs would not have included Avandia on their formularies." Doc. No. 5152 at 4. Therefore, whether GSK concealed information about Avandia, and whether Plaintiffs would have purchased Avandia absent GSK's misrepresentations, was directly relevant to Plaintiffs' arguments.

[49] The Plans have now submitted a declaration from Dr. Abramson properly swearing under penalty of perjury to the information in his three reports. *See* Ex. A to the Decl. of Thomas Sobol in Supp. of Pls.' Resp. in Opp. to GSK's Motion for Continued Sealing [Doc. No. 5270-1] at 4–5.

[50] GSK's Mem. Supp. Mot. for Continued Sealing [Doc. No. 5259] at 5 n.17 (quoting *In re Avandia*, 924 F.3d at 672). Only the Supplemental Expert Statement of Eliot A. Brinton was not included in Plaintiffs' Response to Defendant's Proposed Statement of Undisputed Fact and in GSK's motions that the Third Circuit ruled on. *See* Pls.' Mem. in Opp. to GSK's Motion for the Continued Sealing of the Expert Reports of Austin, Brinton, and Swirsky [Doc. No. 5289] at 3–4. This report will be discussed below.

[51] 836 F.3d 421 (3d Cir. 2016).

[52] GSK's Mem. Supp. Mot. for Continued Sealing [Doc. No. 5259] at 5 n.17.

and usefulness of a document are part of the analysis:

> [T]he issue of whether a document is a judicial record should turn on the use the court has made of it rather than on whether it has found its way into the clerk's file. To be considered a judicial record, to which the common law right of access properly attaches, the item filed must be relevant to the performance of the judicial function and useful in the judicial process in order for it to be designated a judicial document.[53]

However, the dispute in *North Jersey* concerned the disclosure of a letter identifying an unindicted coconspirator sent to a judge's chambers by a prosecutor on the case.[54] The court concluded that because "the letter in question is a part of the general discovery process, it is not subject to any First Amendment or common law right of public access."[55] Here, by contrast, the documents in question are court filings supporting the summary judgment briefing. Thus, *North Jersey* does not provide any basis for the Court to disregard the Third Circuit's holding, in an appeal in this litigation concerning these same documents, that "documents filed in connection with a motion for summary judgment are judicial records."[56]

Moreover, a party cannot "litigate on remand issues that were not raised in a party's prior appeal and that were not explicitly or implicitly remanded for further proceedings."[57] Here, as

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[53] *N. Jersey*, 836 F.3d at 436 (internal quotations and citations omitted).

[54] *See id.* at 424–26.

[55] *Id.* at 425.

[56] *In re Avandia*, 924 F.3d at 672 (citation omitted). Moreover, even if the Third Circuit adhered to a rule limiting the common law right of access to admissible evidence, such a rule would only apply to situations where a court "excluded the documents from consideration." *In re Policy Mgmt. Sys. Corp.*, 67 F.3d 296, at *4 (4th Cir. 1995). Otherwise, documents which the District Court potentially relied upon in reaching its decision would be shielded from public view—thus contravening the purpose of the common law right of access. *See In re Avandia*, 924 F.3d at 672. Here, GSK did not object to the inclusion of the expert reports until after the Court ruled on the summary judgment motion and, as the Plans argue, defects in affidavits are waived when no objections are made. *See St. Marys Area Water Auth. v. St. Paul Fire & Marine Ins. Co.*, No. 04-1593, 2007 WL 1412240, at *6 (M.D. Pa. May 11, 2007) (collecting cases). Therefore, even if GSK is correct that the expert reports were not relevant and were not sworn to under penalty of perjury pursuant to 28 U.S.C. § 1746, its failure to object before the Court's summary judgment decision means that the documents were before the Court when the Court rendered its decision. *See Washington v. Bruraker,* No. 02-106, 2015 WL 6673177, at *4 (W.D. Va. Mar. 29, 2015) ("[T]he mere fact that these documents had been submitted as substantive support for the motion was sufficient to make them judicial.").

[57] *Skretvedt v. E.I. DuPont De Nemours*, 372 F.3d 193, 203 (3d Cir. 2004).

the Plans argue, the Third Circuit's mandate clearly established that the common law right of access applies to the expert reports filed in connection with GSK's motion for summary judgment, and GSK waived the issue that the Abramson Reports are not judicial records.

The "mandate rule" provides that "on remand for further proceedings after [a] decision by an appellate court, the trial court must proceed in accordance with the mandate and the law of the case as established on appeal."[58] As the Plans argue, the Court of Appeals held that:

> It is undisputed that each of the challenged documents are "judicial records" subject to the common law right of access because the parties filed the documents on the District Court's public docket in support of, or in opposition to, GSK's motion for summary judgment . . . As such, the District Court was obligated to apply the exacting common law right of access standard, including the "strong presumption" of access, before granting GSK's motions for continued confidentiality.[59]

GSK argues that "[a] district court may consider, as a matter of first impression, those issues not expressly or implicitly disposed of by the appellate decision,"[60] and that the Court of Appeals "did not explicitly reject GSK's argument that the Abramson reports were not properly part of the summary judgment record and thus not judicial records covered by the common law right of access."[61] Instead, GSK argues that when "the Third Circuit instructed the Court to 'conduct a detailed review of the challenged documents by applying the proper standard for accessibility under the common law,'"[62] the Third Circuit "implicitly requir[ed] the Court to determine whether the Abramson reports were properly part of the summary judgment

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[58] *United States v. Kennedy*, 682 F.3d 244, 252–53 (3d Cir. 2012) (internal quotation marks and citations omitted).

[59] *In re Avandia*, 924 F.3d at 675 (citation omitted).

[60] GSK's Reply Mem. in Supp. of its Motion for the Continued Sealing of Certain Documents [Doc. No. 5275] at 2 (quoting *Skretvedt*, 372 F.3d at 203 n.13).

[61] *Id.* at 2–3. The Court notes that the Court of Appeals likely did not address this argument because, as explained below, GSK failed to properly raise it.

[62] *Id.* at 3 (quoting *In re Avandia*, 924 F.3d at 679).

record."[63] However, the Court declines to read an implicit requirement into the Third Circuit's mandate that contradicts its explicit directives. The Court of Appeals mandated that this Court conduct a document-by-document review and determine whether the presumption of access under the common law can be rebutted—nowhere does the mandate allow the Court to determine that the presumption of access should not be applied. For this reason as well, the Court will apply the common law right of access to the expert reports included in the Third Circuit's mandate.

Furthermore, "an issue is waived unless a party raises it in its opening brief, and for those purposes a passing reference to an issue will not suffice to bring that issue before [the appellate] court."[64] The Plans assert that in its prior appeal to the Third Circuit, GSK failed to raise the argument that the Abramson Reports were not judicial records because they were not sworn to under oath.[65]

GSK points to two places in its appellate brief, as well three parts of the oral argument before the Third Circuit, where it supposedly raised the argument that the Abramson Reports are not "judicial records."[66] GSK's appellate brief did not actually raise this issue, however, and the alleged references at oral argument do not suffice.[67] As an initial matter, both of GSK's

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[63] *Id.*

[64] *Skretvedt*, 372 F.3d at 202–03 (quoting *Laborers' Int'l Union v. Foster Wheeler Corp.*, 26 F.3d 375, 398 (3d Cir. 1994)).

[65] The Plans do not appear to make this argument regarding the other expert reports.

[66] GSK's Reply Mem. in Supp. of its Motion for the Continued Sealing of Certain Documents [Doc. No. 5275] at 2 n.2 (citing Brief of Appellee GlaxoSmithKline LLC, *In re: Avandia Mktg., Sales Practices & Prods. Liab. Litig., No. 18-2259*, at 4 n.3, 23–24 & n.9 (Nov. 28, 2018) (Doc. No. 003113097075) ("GSK Appellate Brief"); Mar. 6, 2019 Argument Tr. at 14:1–15, 15:8–15, 29:15–30:3).

[67] *Skretvedt*, 372 F.3d at 203 (quoting *Laborers' Int'l Union.*, 26 F.3d at 398); *see also Montrose Med. Grp. Participating Sav. Plan v. Bulger*, 243 F.3d 773, 783 (3d Cir. 2001) (holding that an argument was waived "because it was raised for the first time at oral argument."); *In re Stone & Webster, Inc.*, 558 F.3d 234, 247 n.15 (3d Cir. 2009). Moreover, GSK's references at oral argument appear to argue that the Abramson Reports are not relevant, *see, e.g.*, Mar. 6, 2019 Argument Tr. at 15:12–15:15 ("[T]he plaintiffs submitted as an exhibit to that summary judgment motion and they're saying now is public because of that, is a 700-page expert report that has no evidentiary value by any means"), not that the failure to include a sworn declaration rendered them inadmissible.

references to the Abramson Reports in its appellate brief appear in footnotes and "arguments raised in passing (such as, in a footnote), but not squarely argued, are considered waived."[68] Moreover, neither footnote raised the argument that, because Abramson failed to provide a proper sworn declaration, the reports are not judicial records. The first footnoted reference attacks the contents of the reports; it does not make the argument that the reports were not sworn to.[69] The second footnoted reference came in the context of GSK arguing that the First Amendment does not apply to the reports; GSK does not make the argument that the reports were not sworn to and that therefore the common law right of access does not apply.[70] Therefore, because 1) expert reports filed in connection with summary judgment are judicial records; 2) the Third Circuit's mandate requires that the Court apply the common law right of access to these reports; and 3) GSK waived its argument that the Abramson Reports are not judicial records, the Court will apply the common law right of access to these expert reports. However, because Plaintiffs concede that the Supplemental Expert Statement of Eliot A. Brinton is not a judicial record because it was not part of the summary judgment record or included in GSK's motions that the Third Circuit ruled on, the Court will apply the good cause standard of Rule 26 to this report.

B. Application of the Confidentiality Standards to the Expert Reports

"The scale is tipped at the outset in favor of access" to the expert reports filed in connection with summary judgment in order to "promote public confidence in the judicial

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[68] *John Wyeth & Bro. Ltd. v. CIGNA Int'l Corp.*, 119 F.3d 1070, 1076 n.6 (3d Cir. 1997) (citing *Commonwealth of Pa. v. HHS*, 101 F.3d 939, 945 (3d Cir. 1996)).

[69] *See* GSK Appellate Brief at 4 n.3 ("Notably, Plaintiffs want to unseal hundreds of pages of expert reports of John Abramson, which selectively quote and mischaracterize the other documents at issue in an effort to undermine FDA's comprehensive and well-reasoned analysis of the relevant materials.").

[70] *See id.* at 24 n.9 ("Here, not only have the documents at issue not been *admitted* but some – *e.g.*, the hearsay expert reports of John Abramson (SA-0665, SA-1195) – are not even *admissible*.").

system; diminish possibilities for injustice, incompetence, perjury, and fraud; and provide the public with a more complete understanding of the judicial system and a better perception of its fairness."[71]

In arguing that it has overcome the presumption as to all of the expert reports, GSK maintains that unsealing the reports "will jeopardize the health of current Avandia patients by eroding their trust in their doctors' prescribing decisions."[72] According to GSK, "[t]he Abramson Reports are replete with inaccurate, incomplete, and biased representations that would mislead the public about the safety and efficacy of Avandia"[73] and the Austin, Brinton, and Swirsky Reports "on their own are fundamentally misleading in that . . . they fail to account for the current state of the science concerning Avandia's safety" and "are replete with inaccurate, incomplete, and biased representations that would mislead the public about the safety and efficacy of Avandia."[74] GSK argues that it has an interest in keeping the reports sealed because disseminating the allegedly incorrect information in the reports will mislead patients who are still being prescribed Avandia, and cause these patients to "stop their current course of medication without informing their doctor, which in turn will result in adverse outcomes for many of those patients."[75] In support, GSK points to a study in *Diabetes Research and Clinical Practice* that

[71] *In re Avandia*, 924 F.3d at 677 (cleaned up).

[72] GSK's Mem. Supp. Mot. for Continued Sealing [Doc. No. 5259] at 16; GSK's Mem. of Law in Supp. of Motion for the Continued Sealing of the Expert Reports of Austin, Brinton, and Swirsky [Doc. No. 5285] at 14. The Court notes that this is not a harm that GSK itself will suffer. GSK may suffer loss of profits and embarrassment—neither of which are sufficient to overcome the common law presumption of access. *See In re Avandia*, 924 F.3d at 676 ("But we have repeatedly said that concern about a company's public image, embarrassment, or reputational injury, without more, is insufficient to rebut the presumption of public access.") (citation omitted).

[73] GSK's Mem. Supp. Mot. for Continued Sealing [Doc. No. 5259] at 11.

[74] GSK's Mem. of Law in Supp. of Motion for the Continued Sealing of the Expert Reports of Austin, Brinton, and Swirsky [Doc. No. 5285] at 10.

[75] *Id.* at 11.

found that 19.4% of patients who discontinued Avandia in 2007 were not taking any antidiabetic drug six months later.[76]

Even assuming that GSK is correct about the alleged inaccuracies in the reports, it has not met its "burden of showing that the material is the kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure"[77] because "[s]ealing must be based on *current* evidence to show how public dissemination of the pertinent materials *now* would cause the . . . harm."[78] The study GSK cites is "[o]utdated"[79] because it was conducted to determine the effect of the "[c]onsiderable public attention" generated by the association of Avandia with heart conditions and a 2007 FDA safety alert.[80] Thus, the study showed that after the news first broke that a medication taken by many Americans potentially had a life-threatening side effect, 53.3% of people stopped taking it, and 19.4% of those people (about 10% of the people included in the study) were not taking an antidiabetic six months later.[81]

GSK's attempt to impute the findings of this study to the potential effect of unsealing the expert reports at issue here fails for two reasons. First, GSK assumes that the unsealing of expert reports about old news will make the same splash as the original safety alert. The uproar surrounding the original allegations that Avandia could cause adverse health conditions, and that "GSK buried bad study results, misrepresented the truth about Avandia's cardiovascular profile

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[76] *See id.* (citing Ex. F to Decl. of Alexander R. Cobitz, GSK's Mot. for the Continued Sealing of Certain Documents [Doc. No. 5259-6] at 51).

[77] *In re Cendant Corp.*, 260 F.3d at 194 (internal quotation marks and citation omitted).

[78] *In re Avandia*, 924 F.3d at 678 (quoting *In re Cendant Corp.*, 260 F.3d at 196).

[79] *Id.*

[80] *See* Ex. F to Decl. of Alexander R. Cobitz, GSK's Mot. for the Continued Sealing of Certain Documents [Doc. No. 5259-6] at 49.

[81] *Id.* at 51.

to doctors and pharmacy benefit managers, and reaped billions of dollars in profits" was massive.[82] As the Court of Appeals summarized, "[l]awsuits ensued, the United States Food and Drug Administration ("FDA") investigated, and even the United States Senate Finance Committee released a report revealing GSK's misdeeds."[83] Even if, as GSK asserts, "[m]edia outlets will likely report on the release" of the expert reports,[84] it is highly unlikely that the release of these expert reports "rehashing events that played out long ago" will be a front-page news story.[85] Most likely, significantly fewer people will become aware of the release of these reports compared with the publicity surrounding the original safety alert.

Second, even if current Avandia patients learn about the release of the expert reports, it has now been more than thirteen years since the public found out about the potential side effects of Avandia. Most people currently taking Avandia (who number far fewer now than in 2007) are likely already aware of the allegations about Avandia—from conversations with their doctor, friends, family, or the news—and have made a considered choice to take it.[86] In fact, it is hard to imagine that doctors currently prescribing Avandia have not discussed the risks with their patients. Thus, GSK has shown no likelihood that upon learning about the contents of these expert reports, current Avandia patients will suddenly stop taking the drug without consulting a doctor and without substituting another antidiabetic.[87] Taking these two factors together, it is

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[82] *In re Avandia*, 924 F.3d at 669.

[83] *Id.*

[84] GSK's Mem. of Law in Supp. of Motion for the Continued Sealing of the Expert Reports of Austin, Brinton, and Swirsky [Doc. No. 5285] at 11.

[85] GSK's Mem. Supp. Mot. for Continued Sealing [Doc. No. 5259] at 14.

[86] The set of people taking Avandia who are currently oblivious to the explosive allegations about its risks and will learn about the unsealing of expert reports in this MDL is likely miniscule.

[87] Moreover, as GSK's expert declared, "[d]octors prescribe medications to their patients based on their professional judgment, after weighing the risks and benefits of the medication for that particular patient" using the available "clinical data and other scientific information." Decl. of Alexander R. Cobitz, GSK's Mot. for the Continued Sealing of Certain Documents [Doc. No. 5259-6] at 2. Therefore, assuming that the expert reports are out of date and

implausible that unsealing these documents would endanger patients. In sum, the dated study that GSK cites does not demonstrate that disclosure of these expert reports now "will work a clearly defined and serious injury to the party seeking closure."'[88] Therefore, GSK has limited "secrecy interests" in the expert reports.[89]

At the same time, in this long-running MDL "implicat[ing] the public's trust in a well-known and (formerly) widely-used drug," the interests the common law is meant to protect "are particularly important."[90] The interest of promoting "public confidence in the judicial system" demands that information filed in a case impacting such a large segment of the public be readily available.[91] In such a complex and lengthy case "the very openness of the process should provide the public with a more complete understanding of the judicial system and a better perception of its fairness."[92] Therefore, upon balancing the common law presumption of access against GSK's alleged "factor[] militating against access," GSK has failed to meet its burden to maintain the expert reports filed in connection with its motion for summary judgment under seal.[93]

Moreover, GSK has not met its burden under Rule 26 to justify the continued sealing of the Supplemental Expert Statement of Eliot A. Brinton. There is no confidential material in this

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incorrect, doctors will be able to determine this and inform their patients—especially considering that GSK can release the reports of their own experts demonstrating the inaccuracy of the reports at issue here. *C.f. Whitney v. California*, 274 U.S. 357, 377 (1927) (Brandeis, J., concurring) ("If there be time to expose through discussion the falsehood and fallacies, to avert the evil by the processes of education, the remedy to be applied is more speech, not enforced silence."), *overruled in part by Brandenburg v. Ohio*, 395 U.S. 444 (1969) (per curiam).

[88] *In re Cendant Corp.*, 260 F.3d at 194 (quoting *Miller*, 16 F.3d at 551).

[89] *In re Avandia*, 924 F.3d at 673 (quoting *Leucadia,* 998 F.2d at 167).

[90] *Id.* at 677.

[91] *Leucadia,* 998 F.2d at 161 (quoting *Westinghouse*, 949 F.2d at 660).

[92] *Id.* (quoting *Westinghouse*, 949 F.2d at 660).

[93] *In re Cendant Corp.*, 260 F.3d at 194 (quoting *Leucadia,* 998 F.2d at 165). Accordingly, the Court need not decide whether the First Amendment right of access applies to these documents. *See In re Avandia*, 924 F.3d at 680 ("If on remand the District Court concludes that any of the sealed documents merits continued confidentiality under the common law right of access, then the Court should also consider the parties' arguments regarding the First Amendment right of public access."

report and the issues involved are important to the public, both in terms of the public's interest in open proceedings and in public health and safety.[94] Moreover, the Court has determined that the other challenged expert reports, including Brinton's original report, must be unsealed pursuant to the common law right of access, and there is no indication that the unsealing of this particular report would cause GSK any separate harm. Therefore, the public interest in disclosure outweighs GSK's private interest in confidentiality.

C. Application of the Common Law Right of Access to the Requested Redactions

Exhibit D to GSK's Motion for Continued Sealing contains a list of 55 documents—including clinical studies, GSK submissions to the FDA, internal GSK emails and letters, records of teleconferences between GSK and the FDA, Avandia presentations and plans, and some court filings in the MDL—that GSK asserts "contain the names, emails, phone numbers, addresses, identification numbers, and other personal information of study subjects, GSK employees, and third-party individuals, which must be redacted to protect their privacy rights under European Union ('EU') law."[95] Although GSK is a United States entity, its parent, GlaxoSmithKline plc, is registered in England and Wales, and has affiliates throughout the EU. GSK's argument is essentially that EU regulations provide a basis to overcome the presumption of access because "data transmitted to the parent company or submitted to European regulators is subject to European privacy laws," including European Medicines Agency (EMA) Policy 0070 and the

[94] *See Glenmede*, 56 F.3d at 483 (citing *Pansy,* 23 F.3d at 787–91).

[95] GSK's Mem. Supp. Mot. for Continued Sealing [Doc. No. 5259] at 16. Specifically, GSK argues that "study subjects' pseudonymized identification numbers . . . date and month of birth; subject event or assessment dates when the study day is present; investigator names and geographic locations of investigator sites; names, initials, signatures, email, phone/fax number, and staff ID numbers for GSK, vendor, and other company personnel, except the names and initials of signatories to clinical documents; the signature, email, phone/fax number, site/investigator identifier, name, initials, organizational title and department, institutional website URL, address, and curriculum vitae of the investigator and site staff; and the name, initials, signature, email, phone/fax number and staff ID of other individuals" should be redacted. *Id.* at 19–20.

EU's General Data Protection Regulation (GDPR).[96] Therefore, GSK argues that the harm justifying the redactions is the "effective, proportionate and dissuasive" penalties it would be subject to under EU law.[97]

As an initial matter, the parties dispute whether GSK waived this argument too. The Plans argue that GSK's appellate brief does not mention European Union law while GSK argues that its brief extensively argued that these documents should be redacted.[98] Because the Court of Appeals directed this Court to "conduct a detailed review of the challenged documents by applying the proper standard for accessibility under the common law," the Court will consider GSK's argument that EU law requires redaction despite the common law presumption of access.[99]

Federal Rule of Procedure 44.1 controls the application of foreign law in federal court and provides:

> A party who intends to raise an issue about a foreign country's law must give notice by a pleading or other writing. In determining foreign law, the court may consider any relevant material or source, including testimony, whether or not submitted by a party or admissible under the Federal Rules of Evidence. The court's determination must be treated as a ruling on a question of law.[100]

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[96] GSK's Mem. Supp. Mot. for Continued Sealing [Doc. No. 5259] at 17.

[97] GSK's Reply Mem. in Supp. of its Motion for the Continued Sealing of Certain Documents [Doc. No. 5275] at 6 (quoting Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L 119/1, at 84(1), available at https://gdprinfo.eu/).

[98] *See* GSK Appellate Br. at 34–35, 51.

[99] *In re Avandia*, 924 F.3d at 679 (citing *Leucadia,* 998 F.2d at 167). GSK originally only argued that its obligation to comply with EU law provides sufficient basis to overcome the presumption of access. Only in subsequent briefing did GSK supplement its argument to rest on the harm it would suffer in the form of monetary penalties under EU law. As explained below, however, regardless of form, GSK's argument is unavailing.

[100] Fed. R. Civ. P. 44.1; *see also Animal Sci. Prods., Inc. v. Hebei Welcome Pharm. Co. Ltd.*, 138 S. Ct. 1865, 1869–70 (2018)*; Bel–Ray Co., Inc. v. Chemrite Ltd.*, 181 F.3d 435, 440 (3d Cir. 1999) ("This rule provides courts with broad authority to conduct their own independent research to determine foreign law but imposes no duty upon them to do so."). "Under Rule 44.1, it is the responsibility of the party seeking application of foreign law to 'carry both the burden of raising the issue that foreign law may apply in an action, and the burden of adequately proving foreign

With regard to the disputed proposed redactions, the Plans assert 1) that the EMA and GDPR do not apply to this information and 2) that, even if they do, U.S. law takes precedence over the EU regulations.

Even if the EMA and GDPR would otherwise apply, the information at issue here falls outside the scope of the regulations. EMA Policy 0070 only applies to "clinical data submitted to the Agency" after January 1, 2015, and all of the clinical data in these cases were published before that date.[101] Similarly, the GDPR did not take effect until May 25, 2018.[102] As the Court granted GSK's motion for summary judgment on December 7, 2017, any actions by GSK with regard to the documents occurred before the GDPR took effect. Thus, because GSK would not be subject to penalties under EU law, its limited "secrecy interests" in the disputed requested redactions cannot overcome the strong presumption of access that applies in this case.[103]

The Court notes that even if the EU regulations did apply to the disputed documents, American law must take precedence here. In the analogous context of the production of discovery, "the United States Supreme Court expressly stated that a foreign statute does 'not deprive an American court of the power to order a party subject to its jurisdiction to produce evidence even though the act of production may violate that statute.'"[104] "Rather, in this scenario, the Court employs a comity analysis . . . to weigh 'the interests of the United States and

law to enable the court to apply it in a particular case."' *Incubadora Mexicana, SA de CV v. Zoetis, Inc.*, 116 F. Supp. 3d 519, 526 (E.D. Pa. 2015) (quoting *Bel–Ray*, 181 F.3d at 440).

[101] European Medicines Agency, *Clinical Data Publication*, https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication (last visited September 1, 2020).

[102] European Commission, *Data protection in the EU*, https://ec.europa.eu/info/law/law-topic/data-protection/data-protection-eu_en (last visited September 1, 2020).

[103] *In re Avandia*, 924 F.3d at 673 (quoting *Leucadia,* 998 F.2d at 167).

[104] *AstraZeneca LP v. Breath Ltd.*, No. 08-1512, 2011 WL 1421800, at *11 (D.N.J. Mar. 31, 2011) (quoting *Societe Nationale Industrielle Aerospatiale v. United States District Court for the Southern District of Iowa*, 482 U.S. 522, 544 n.29 (1987)).

the party seeking discovery against the foreign state's interest in secrecy.'"[105] "[A] court may, within its discretion, deny comity . . . if it finds that the extension of comity 'would be contrary or prejudicial to the interest of the' United States."[106]

The United States has a deep interest in preserving the common law right of access, which "antedates the Constitution."[107] "The underpinnings of the . . . common law right[] of access are historical experience and societal utility."[108] As explained above, the right serves the weighty interests of promoting "public confidence in the judicial system"; diminishing possibilities for "injustice, incompetence, perjury, and fraud"; and providing the public with a "more complete understanding of the judicial system and a better perception of its fairness."[109] As the Third Circuit explained, these "interests are particularly important in a case such as this one, which implicates the public's trust in a well-known and (formerly) widely-used drug."[110] These interests are especially acute when it comes to the specific documents at issue because the information GSK seeks to redact includes records submitted to the FDA, the federal agency tasked with protecting the public from harmful drugs, by a U.S. corporation concerning the regulation of a drug in this country.[111] Therefore, even if the regulations otherwise could be

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[105] *In re Mercedes-Benz Emissions Litig.*, No. 16-881, 2020 WL 487288, at *6 (D.N.J. Jan. 30, 2020). "International comity is 'the recognition which one nation allows within its territory to the legislative, executive, or judicial acts of another nation, having due regard both to international duty and convenience, and to the rights of its own citizens or of other persons who are under protection of its laws.'" *In re Nazi Era Cases Against German Defendants Litig.*, 129 F. Supp. 2d 370, 386 (D.N.J. 2001) (quoting *Hilton v. Guyot*, 159 U.S. 113, 143 (1895)).

[106] *Phila. Gear Corp. v. Phila. Gear de Mexico, S.A.*, 44 F.3d 187, 191 (3d Cir. 1994); *see also Somportex Ltd. v. Philadelphia Chewing Gum Corp.*, 453 F.2d 435, 440 (3d Cir. 1971); *In re Nazi Era Cases*, 129 F. Supp. 2d at 387 ("[D]omestic courts should withhold comity only when its acceptance would be contrary or prejudicial to the interest of the United States.").

[107] *Bank of Am.*, 800 F.2d at 343.

[108] *United States v. Smith*, 776 F.2d 1104, 1114 (3d Cir. 1985).

[109] *In re Avandia*, 924 F.3d at 677 (quoting *Littlejohn v. Bic Corp.*, 851 F.2d 673, 678 (3d Cir. 1988)).

[110] *Id.*

[111] The Court also notes that considering the broad scope of the GDPR, GSK's argument could allow all U.S. corporations with a presence in the EU to render the right of access a nullity.

determined to apply, the extension of comity would be contrary or prejudicial to the interest of the United States.[112] Because there is no basis in U.S. law to overcome the strong presumption of access to judicial records[113] other than a privacy interest in certain personal information that Plaintiffs do not object to redacting,[114] GSK's motion will be granted only to that limited extent.

IV. CONCLUSION

Justice Brandeis famously declared that "sunlight is the most powerful of all disinfectants."[115] Considering the common law presumption of public access, the lack of harm GSK will face, the significance of this litigation, and the number of people affected, light must shine on these documents. Therefore, for the reasons stated above, GSK's Motion for the Continued Sealing of Certain Documents will be granted only as to the redaction of personal information of study subjects and employee telephone numbers, addresses, and the ending of email addresses and otherwise denied, and GSK's Motion for the Continued Sealing of the

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[112] *See Phila. Gear Corp.*, 44 F.3d at 191.

[113] At the very end of its memorandum, in a single sentence, GSK makes its only non-EU law argument and states that "[n]ot only does EU law clearly set forth the need to protect individuals' privacy rights, but GSK employees have been identified and targeted in acts of violence and terroristic threats because of their employment at GSK GSK's Mem. Supp. Mot. for Continued Sealing [Doc. No. 5259] at 20. In an attached affidavit, GSK links to three news articles about animal rights activists targeting GSK executives. *See* Decl. of Tamsin Sargood, Ex. G to GSK's Mot. for Continued Sealing of Certain Documents [Doc. No. 5259-7] at 3 n.5. However, the most recent of those articles is from over 14 years ago, *see id.*, and the Third Circuit has explained that "[o]utdated evidence . . . is insufficient to overcome the presumption of public access" because sealing must be based on current evidence showing how public dissemination would now cause harm. *In re Avandia*, 924 F.3d at 678.

[114] *See Moore v. CVS RX Servs.*, 660 F. App'x 149, 153 n.4 (3d Cir. 2016) ("In light of the District Court's treatment of the medical information and because in this instance, the right to privacy outweighs the public's right of access to materials filed in litigation, we grant CVS's motion for leave to file those records under seal."). The Plans do not object to the redaction of personal information of study subjects or "employee telephone numbers, addresses, or the ending of email addresses." Pls.' Mem. Opp. to GSK's Mot. for Continued Sealing of Certain Documents [Doc. No. 5269] at 16. Therefore, the Court will grant GSK's request that this information—in the documents listed in Exhibit D to GSK's Motion for Continued Sealing and in the Abramson Reports—be redacted. *See* GSK's Mem. Supp. Mot. for Continued Sealing [Doc. No. 5259] at 13 n.41 ("Even if the Court holds that the Abramson Reports should not be excluded in their entirety, they should be redacted to protect individuals' privacy interests."). Moreover, because the Plans do not dispute redacting this information, there is no need to determine whether the First Amendment applies to these documents.

[115] *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 305 (1964); *see also PG Pub. Co. v. Aichele*, 705 F.3d 91, 111 (3d Cir. 2013).

Expert Reports of Donald Austin, Eliot Brinton, and Brian Swirky will be denied. An order will be entered.